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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/591,582 | 05/23/2007 | Claude LeLouarn | 58767.000016 | 3374 |
| 21967 7590 11/20/2007 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109 | | | EXAMINER FLOOD, MICHELE C | |
| | | | ART UNIT 1655 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,582

Applicant(s)

LELOUARN, CLAUDE

Examiner

Michele Flood

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/5/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 5, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating or reducing hair growth in a patient suffering hirsutism comprising administering an effective amount of botulinum toxin to said person in need thereof, does not reasonably provide enablement for either a method of preventing hair growth in a person with hypertrichosis or a patient suffering from hirsutism or a cosmetic treatment method intended to prevent hair growth in person in want of such treatment or in a cosmetic treatment intended to prevent hair growth in a pet comprising administering an amount of botulinum toxin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2D 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the

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state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Nature of the Invention. The claims are drawn to a method for preventing hair growth in a person with hypertrichosis or in a patient suffering from hirsutism comprising administering a botulinum toxin to said person or patient. The claims are further drawn to a method wherein the botulinum toxin is a botulinum toxin of type A, B or F. The claims are drawn to a cosmetic treatment method intended to prevent hair growth in a person wanting such a treatment comprising administering to an area to be treated a pharmaceutical composition including botulinum toxin in an effective quantity. The claims are further drawn to a cosmetic treatment method wherein the botulinum toxin wherein the botulinum toxin is a botulinum toxin of type A, B and F; and wherein the composition is applied to an area of the body including the torso, the legs, the arms, the armpits or the face. The claims are drawn to a cosmetic treatment method intended to prevent hair growth in a pet comprising administering to an area to be treated a pharmaceutical composition including botulinum toxin in an effective quantity.

Breadth of the Claims. The claims are broad in that the claims are drawn to a methods of preventing hair growth in a person with hypertrichosis or hair growth in a patient with hirsutism, as well as cosmetic treatments intended to prevent hair growth in a person or a pet comprising administering any and all amounts of any and all

botulinum. The complex nature of the subject matter of the invention is clearly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples. Applicant has reasonably demonstrated a method of reducing downy hairs on the upper lip of a patient seeking hair growth treatment comprising administering a solution containing 3 units of BOTOX™ (Allergan, France; Botulinum toxin type A) to several points of the epidermis situated just above the red of their upper lip. For example, on page 4 of the present specification under “*EXAMPLE*”, Applicant discloses that such administration presented less downy hair on the upper in a follow-up observation, four months later. Given the foregoing, it appears that Applicant has demonstrated a method of treating hirsutism comprising administering an effective amount of a pharmaceutical composition comprising botulinum toxin A via injection to the upper lip of a person in need thereof wherein the administering of the claim-designated pharmaceutical composition reduced downy hairs on the upper lip of the treated person, given that the presence “downy hairs” on the upper lip of a patient is often associated with hirsutism whereas hypertrichosis is generally characterized by the presence of vellus, “downy hairs” growing evenly over the body. However, nowhere in the originally filed specification has Applicant demonstrated methods for the prevention of hair growth in subjects with either hypertrichosis or hirsutism and/or cosmetic treatments intended for the prevention of hair growth in a person in want of such treatment or in a pet comprising the administration of effective amounts of any botulinum toxin of type A, B or F, as broadly claimed by Applicant.

The specification envisions that the instantly cosmetic treatment methods are useful in preventing hair growth in a person with hypertrichosis or preventing hair growth in a person suffering from hirsutism or preventing hair growth in a person seeking such treatment or preventing hair growth in a pet comprising administering a pharmaceutical composition comprising an amount of any and all types of botulinum effective to provide a therapeutic effect for preventing hair growth. However, nowhere in the specification as originally filed is there a *single example*, either working or prophetic, which indicates that the claimed invention would actually provide a method comprising administering the claim-designated ingredients for the aforementioned beneficial functional effects of preventing hair growth. Moreover, no working examples are provided which demonstrate the efficacy of the instantly claimed composition to prevent the occurrence of hair growth in a subject with hypertrichosis, hirsutism or hair growth in any subject. Nowhere in the specification is there any indication that the instantly claimed composition would actually act as an agent for the prevention of hair growth. While the administration of the claim-designated ingredients to a mammal may be useful as a method to reduce the growth of hair in a subject in need thereof comprising administering an effective amount of botulinum toxin A, it is highly unlikely that the claimed method can prevent hair growth in a person with hypertrichosis, hirsutism or hair growth in mammals comprising the administration of any and all amounts of any and all types of botulinum toxin to said mammals. Moreover, it would be highly unpredictable to ascertain whether the composition of the present invention could 'prevent' hair growth in either a subject wanting such treatment or prevent hair growth in

a pet, much less prevent the occurrence of hair growth in persons suffering from either hypertrichosis or hirsutism. Although the present claims recite 'prevent', prevention is deemed to be a 'cure' since prevention of a disease or a disease condition is interpreted to mean that the disease will cease to exist after administration of the drug. To 'prevent' is deemed to mean that the composition of the present invention would in all cases cease the disease from occurring in a patient. The instant specification is lacking any specific working example where botulinum toxin has substantially 'prevented' hair growth in persons suffering either hypertrichosis or hirsutism or any other subject. Therefore, lacking this guidance, it would require a substantial inventive contribution by one of ordinary skill in the art in order to practice the invention as claimed.

Predictability and State of the Art. The state of the art at the time the invention was made was unpredictable and underdeveloped. For instance, the state of the art at the time of filing indicated there was no cure for either hypertrichosis or hirsutism, as evidenced by the teachings of (U) and (V). Moreover, it should also be noted that the state of the art at the time of filing of the present specification suggests that the delivery of cosmetics or pharmaceuticals comprising botulinum toxin for the prevention of hair growth in subjects teaches away from the instantly claimed methods of treatment since Maurer (A*) teaches a process for improving hair growth in humans comprising the injection of botulinum toxin to subjects.

There is no guidance in the specification, other than the aforementioned example directed to the use of botulinum toxin A for reducing the hair growth of downy hairs in a patient. Accordingly, in view of the breadth of the claims, the lack of guidance provided

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by the specification, the lack of working examples, and the lack of correlative working examples, as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method, as broadly claimed by Applicant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 10 recite the limitation "the administration". There is insufficient antecedent basis for this limitation in the claims.

Claims 6 and 10 recite the limitation "the area of the body" in line 2. There is insufficient antecedent basis for this limitation in the claims.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
November 14, 2007

Michele P. Flood
MICHELE FLOOD
PRIMARY EXAMINER